DEPARTMENT OF HEALTH & HUMAN SERVICES

New York District

Food & Drug Administration
300 Pearl Street
Buffalo, NY 14202

November 7, 2000

WARNING LETTER NYK 2001-13

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Arthur Gianakos, President
North American Medical Products, Inc.
3 Walker Way
Albany, NY 12205

Dear Mr. Gianakos:

Inspections of your facility, performed 3/30-4/19/00 and 9/16-11/1/99 by Food and Drug Administration (FDA) Investigator Michael J. Sinkevich, included collection of information related to your Safe-Point Needle Cover. Review of this information by personnel at our Center for Devices and Radiological Health confirmed that this product, which is made and marketed by your firm, is in violation of both adulteration and misbranding provisions of the Federal Food, Drug and Cosmetic Act (the Act).

Under this United States Federal Law, this product is considered to be a medical device because it is used to diagnose or treat a medical condition or to affect the structure or function of the body. The law requires that manufacturers of medical devices obtain marketing clearance for their products from FDA before they may offer them for sale. This helps protect the public health by ensuring that new medical devices are shown to be either safe and effective or substantially equivalent to other devices already legally marketed in this country.

Our records do not show that you obtained marketing clearance before you began offering your product for sale. The kind of information you need to submit in order to obtain this clearance is described in the enclosed materials. The FDA will evaluate this information and decide whether your product may be legally marketed.

Because you do not have marketing clearance from FDA for modifications made to the Safe-Point Needle Cover, marketing your product is a violation of the law. In legal terms, the product is adulterated under section 501(f)(1)(B) and misbranded under section 502(o) of the Act. Your product is adulterated under the Act because you did not obtain premarket approval based on information developed by you that shows your device is safe and effective. Your product is misbranded under the Act because you did not submit the information that shows your device is substantially equivalent to other devices that are legally marketed.

You should take prompt action to correct these and all violations at your firm. Failure to achieve prompt corrective action may result in regulatory action - without further notice. These actions include, but are not limited to, seizing your product inventory, obtaining a court injunction against further marketing of the product, or assessing civil money penalties. Also, other Federal Agencies are informed about the warning letters we issue, such as this one, so they may consider this information when awarding government contracts.

It is necessary for you to take action on this matter now. Please notify this office in writing, within fifteen (15) days, of the specific steps you have taken to correct the noted violations and to prevent a recurrence of similar violations. Your response should also include your plan for bringing products into compliance that were distributed prior to obtaining marketing clearance from FDA.

Your response should be directed to James M. Kewley, Compliance Officer, at the above address. If you have further questions, you may contact Mr. Kewley by telephone at (716) 551-4461 Ext. 3128.

Sincerely,

Edward W. Thomas
Acting District Director

Enclosure: Office of Device Evaluation Publication
"Deciding When to Submit a 510(k) for a Change to an Existing Device"